and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 62 FR 67271, Dec. 24, 1997]

§ 5.50 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the act (except for petitions submitted in response to FEDERAL REGISTER notices initiating standard-setting under section 514(b) of the act or premarket approval under section 515(b) of the act):

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 54 FR 11866, Mar. 22, 1989; 62 FR 67271, Dec. 24, 1997]

§ 5.51 Determination of classification of devices.

(a) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device in commercial distribution prior to May 28, 1976, pursuant to section 513(d) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, pursuant to section 513 (f)(1)(A) of the act:

(1) The Director and Deputy Directors, CDRH, and the Director, Deputy Directors, Chief of the Premarket Notification Section, Division and Deputy Division Directors, Associate Division Directors, and Branch Chiefs, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, CBER.

[55 FR 6974, Feb. 27, 1990, as amended at 60 FR 2014, Jan. 6, 1995; 62 FR 67271, Dec. 24, 1997]

§ 5.52 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 62 FR 67271, Dec. 24, 1997]

§ 5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices